January 6, 2015

# KaloBios Reports Top-Line Data for Phase 2 Study of KB001-A to Treat Pseudomonas Aeruginosa Lung Infections in Cystic Fibrosis Patients

## Study Does Not Meet Primary Endpoint

SOUTH SAN FRANCISCO, Calif., Jan. 6, 2015 /PRNewswire/ -- KaloBios Pharmaceuticals, Inc. (Nasdaq: KBIO) today announced top-line data from the randomized, double-blind, placebo-controlled Phase 2 study of KB001-A, an anti-PcrV monoclonal antibody (mAb) fragment, to treat *Pseudomonas aeruginosa* (*Pa*) lung infections in subjects with cystic fibrosis (CF). While the data from this study showed KB001-A was generally safe and well-tolerated, the primary endpoint of increased time to need for antibiotics for worsening respiratory tract signs and symptoms (an indicator of reduction of the risk to develop pulmonary exacerbations) was not met.

The company also evaluated time to need for antibiotics in a number of pre-specified subgroup analyses known to be associated with such risk and none demonstrated an improvement for KB001-A versus placebo. In addition, secondary endpoints such as improvements in $FEV_1$ and subject-reported outcomes as measured by Cystic Fibrosis Respiratory Symptom Diary (CFRSD) did not show an advantage with KB001-A treatment.

"The study did demonstrate a non-significant reduction in*Pa* titer in sputum measured post dosing and a 3% improvement in $FEV_1$ (p=0.0029) at Week 16 for the KB001-A arm compared to placebo; however, these effects were not accompanied by improvements in other clinically significant end-points such as exacerbations or symptoms," said Nestor A. Molfino, MD, MSc., KaloBios' Chief Medical Officer. "The KaloBios team is still collecting all of the patient data and working to further understand the results and plan to submit our comprehensive findings to a scientific meeting or journal."

"We are very disappointed that KB001-A did not demonstrate a clinically significant effect on *Pa* infections in these CF patients, but we are thankful to all of them for volunteering to participate in this study," said David W. Pritchard, KaloBios' President and Chief Executive Officer. "Based on these top line data, we intend to discontinue our development of KB001-A in cystic fibrosis."

"Going forward, KaloBios will focus resources and efforts on advancing our oncology programs. Specifically, we are working to advance our KB004 oncology program as well as to expand the oncology development portfolio with the possible introduction of additional oncology indications for KB004 or for KB003, our anti-GM-CSF antibody. Currently, the KB004 Phase 2 cohort expansion study evaluating subjects with myelofibrosis, myelodysplastic syndrome, and acute myeloid leukemia is actively enrolling," said Mr. Pritchard.

**Conference Call with Management**
Management will host a teleconference and webcast to provide an overview of the trial results later today, January 6, 2015, at 4:30PM Eastern Time (1:30PM Pacific Time). Interested parties can listen to the live teleconference by dialing (800) 514-4861 from the U.S. and Canada or +1 (678) 809-2406 for international callers. Individuals may access the live audio webcast by visiting the event URL at: http://ir.kalobios.com/events.cfm. A replay of the webcast will be available on the company's website for 90 days following the live event.

**KB001-A Trial Design**
The Phase 2 clinical study of KB001-A in CF subjects with*Pa* lung infections was a randomized, double-blind, placebo controlled study in which 182 subjects were randomized one to one between treatment with KB001-A or placebo. Eligible subjects were identified as CF patients whose lungs were colonized with *Pa* at the time of entry into the study, and who had been compliant in taking their antibiotics for at least the preceding two cycles. Subjects enrolled in the 16 week study were allowed to continue on their antibiotics in the first four weeks of the study, after which antibiotics were withdrawn for the remainder of their time on the study. Throughout the 16 week study duration, subjects received either placebo or KB001-A dosed at 10 mg/kg every four weeks via intravenous administration with one additional loading dose at Week 2. The primary endpoint of the study was the time to need for antibiotics for respiratory signs and symptoms and was analytically expressed as a hazard ratio.

**About KaloBios**

KaloBios Pharmaceuticals, Inc. is developing a portfolio of proprietary, patient-targeted, first-in-class monoclonal antibodies designed to treat severe life-threatening or debilitating diseases for which there is an unmet medical need, with a focus on cancer.

KaloBios has advanced three programs to clinical development:

- KB004 is an anti-EphA3 mAb with the potential to treat hematologic malignancies and solid tumors. KaloBios is conducting a Phase 1/2 study evaluating KB004 in hematologic malignancies. The Phase 1 dose escalation portion of the study in subjects with hematologic malignancies is fully enrolled, and KaloBios has initiated the Phase 2 expansion portion of the study. The Phase 2 study, which is screening patients for EphA3 expression, is currently focused on patients with myelofibrosis (MF), myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML). KaloBios is evaluating other potential oncology indications for KB004, including additional hematologic malignancies as well as solid tumors.
- KB003 is an anti-GM-CSF mAb with the potential to treat inflammatory diseases,

which KaloBios had previously been developing in severe asthma. KaloBios is currently evaluating the potential of this compound in oncology indications where GM-CSF may play a key role such as chronic myelomonocytic leukemia (CMML) to determine if there is adequate scientific rationale to commence clinical evaluation of KB003 in an oncology setting.

- KB001-A is an anti-PcrV mAb fragment that was being developed for the prevention and treatment of *Pseudomonas aeruginosa* (*Pa*) infection. KaloBios conducted a 182 patient Phase 2 study in cystic fibrosis (CF) subjects with chronic *Pa* lung infection which did not meet its primary endpoint. As a result, KaloBios has discontinued development of KB001-A in CF patients. KaloBios had received Orphan Drug designation from both the U.S. FDA and the European Medicines Agency for KB001-A for the treatment of *Pa* lung infection in CF patients, and had also received Fast Track Status from the U.S. FDA for the investigation of KB001-A for the protection against bacterial pneumonia caused by *Pa* in mechanically ventilated patients. KaloBios will continue to seek a partner that may be interested in advancing this program.

All of the company's antibodies were generated using its proprietary Humaneered® technology, a method that converts nonhuman antibodies (typically mouse) into recombinant antibodies that have a high binding affinity to their target and are designed for chronic therapeutic use. The company believes that antibodies produced using its Humaneered® technology offer important clinical and economic advantages over antibodies generated by other methods in terms of high binding affinity, high manufacturing yields, and minimal to no immunogenicity (inappropriate immune response) upon repeat administration in humans.

For more information on KaloBios Pharmaceuticals, please visit our web site at http://www.kalobios.com.

***Forward Looking Statements***

*This release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, and statements regarding the company's clinical development of KB001-A, KB004 and KB003. Forward-looking statements reflect management's current knowledge, assumptions, judgment and expectations regarding future performance or events. Although management believes that the expectations reflected in such statements are reasonable, they give no assurance that such expectations will prove to be correct and you should be aware that actual results could differ materially from those contained in the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties including, but not limited to, the potential timing and outcomes of clinical studies of KB001-A and KB004 undertaken now or in the future; the company's limited cash reserves and its ability to obtain additional capital on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials that the company has initiated or plans to initiate; the ability of the company to timely source adequate supply of its development products from third party manufacturers on whom the company depends; the potential, if any, for future development of KB003; the company's ability to successfully progress, partner or complete further development of its programs; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory*

*approvals; the company's ability to protect the company's intellectual property; competition; changes in the regulatory landscape or the imposition of regulations that affect the company's products; and other factors listed under "Risk Factors" in the company's most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 6, 2014, the Annual Report on Form 10-K filed on March 13, 2014, and the company's other filings with the Securities and Exchange Commission.*

*All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this release. The company has no obligation, and expressly disclaims any obligation to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.*

For more information, visit http://www.kalobios.com.

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